REMARKS

Applicants have received and reviewed the Office Action dated August 14, 2009. Applicants request entry of this amendment and reconsideration of the rejection of the claims.

Claims 29, 39-40, 48-49, 57-58, and 63-64 have been amended. New claims 68-69 have been added. Applicants submit that the amendments and new claims are supported throughout the specification including at page 20, lines 20-21; page 21, lines 12, 19, 23, and 25; Tables 2 and 3; and paragraph 170 in the published version.

35 U.S.C. § 112

Claims 29, 30, 32 and 67 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. While not acquiescing to the rejection and solely to expedite prosecution, the claims as amended address the rejection. Applicants request withdrawal of this rejection.

35 U.S.C. § 102(b)

Claims 29 and 30 were rejected under 35 U.S.C. § 102(b) as anticipated by Vaughan-Thomas et al., 2001. Applicants traverse the rejection.

"Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." Lindemann Mashinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984); See also, MPEP §2131. Applicants submit that cited reference does not disclose all of the elements of the rejected claims.

Applicants claim 29 is now directed to a composition for treating or preventing arthritis or other degenerative disease, said composition comprising one or more substantially purified polypeptides having at least 65% amino acid identity to SEQ ID NO: 14 and having an amino acid length of less than 250 amino acids, in combination with a physiological acceptable carrier, wherein the polypeptide comprises one or more polypeptide fragments selected from:(a) KSVSFSYKG (SEQ ID NO: 2);(b) KIMIGVERS (SEQ ID NO: 3);(c) RIESLPIKPRG (SEQ ID NO: 5);(d) KHWSIWQIQDSSGKE (SEQ ID NO: 6);(e) RIGQDDLPGFDLISQFQIDKA (SEQ ID NO: 7); (f) RHLYPNGLPEEYSFLTTFRM (SEQ ID NO: 8);(g) KGLDGSLQTAAFSNLPSLFDSQWHKI (SEQ ID NO: 9); (h) RSSATLFVDCNRI (SEQ ID NO: 11); and (i) KLGNNVDFRI (SEQ ID NO: 4); and wherein the polypeptide induces tolerance to cartilage.

The cited reference does not disclose the compositions as claimed. The cited reference fails to disclose a composition comprising one or more substantially purified polypeptides. The reference discloses a deduced partial amino acid sequence. The Examiner suggests that since the publication does not state that the sequence is deduced from cDNA, it can therefore be assumed that the protein must be in a composition. Applicants disagree. A person skilled in the art would know from reading the publication that the sequence deposited was a nucleotide sequence and that the disclosed amino acid sequence is a predicted amino acid sequence only.

Applicants submit that a person skilled in the art would understand that a substantially purified protein had not been produced. In our view, the disclosure of a predicted amino acid sequence is not the disclosure of a substantially purified protein. An amino acid sequence does not disclose or suggest translational modifications such as glycosylation. It is well known that glyosylation is important to determining the correct folding and stability of a protein. Therefore, the amino acid sequence does not predict the functional protein.

In addition, there is no disclosure of the property of the polypeptide of inducing tolerance to cartilage. The examiner contends that this is an intended use. However, applicants submit that this is a property of the compositions as claimed. Cartilage may be considered as an anisotropic biomaterial composed essentially of a three-dimensional fibrous network of type II collagen fibrils copolymerized with types IX and XI collagens embedded in a proteoglycan (PG) rich hydrated extracellular matrix. Type II collagen accounts for over 90% of the total collagen of adult cartilage while type IX cartilage is only 1-2%. In addition to the collagens and proteoglycans, cartilage also contains a large number of non-collagenous proteins, the most abundant being cartilage oligomeric protein (COMP), cartilage matrix protein (CMP), and thrombospondin. The cited reference provides no information or technical reasoning to support the view that any components of cartilage much less the claimed compositions have the property of inducing tolerance to cartilage.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. MPEP §2112. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The prior

inherent characteristic must be established as a certainty, probabilities are not sufficient. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981).

Based on the foregoing, Applicants request withdrawal of this rejection.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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